

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ENZO LIFE SCIENCES, INC., :  
 :  
Plaintiff/Counterclaim Defendant, : Civil Action No. 02-212-JJF  
 :  
 v. :  
 :  
DIGENE CORPORATION, :  
Defendant/Counterclaim Plaintiff :  
 v. :  
ENZO BIOCHEM, INC., :  
 :  
Additional Counterclaim Defendant. :

---

Josy W. Ingersoll, and Sara Beth Reyburn Esquires of YOUNG,  
CONAWAY, STARGATT & TAYLOR, L.L.P., Wilmington, Delaware.  
Of Counsel: Richard L. DeLucia, Jeffrey M. Butler, and Paul M.  
Richter, Jr., Esquires of KENYON & KENYON, New York, New York.

Attorneys for Plaintiff, Enzo Life Sciences, Inc. and Additional  
Counterclaim Defendant, Enzo Biochem, Inc.

Richard D. Kirk, Esquire of MORRIS, JAMES, HITCHENS & WILLIAMS  
L.L.P., Wilmington, Delaware.  
Of Counsel: Mark R. Labgold, Ph.D., Kevin M. Bell, Laura A.  
Donnelly, Esquires of PATTON BOGGS L.L.P., McLean, Virginia.  
Richard J. Oparil, Esquire of PATTON BOGGS L.L.P., Washington,  
DC.

Attorneys for Defendant, Digene Corporation.

---

**MEMORANDUM OPINION**

July 3, 2003  
Wilmington, Delaware

**FARNAN, District Judge**

Currently pending is Digene Corporation's ("Digene") Motion For Leave to Amend Its Answer and Counterclaims (D.I. 83). For the reasons discussed, the motion will be granted.

**I. Factual Background**

This is a patent infringement action brought by Plaintiff Enzo Life Sciences, Inc. ("Enzo") against defendant Digene involving U.S. Patent No. 6,221,581B1 (the "'581 Patent"), issued on April 24, 2001. Both Enzo and Digene are companies involved in the development, manufacture and distribution of proprietary RNA and DNA testing systems. The '581 Patent concerns hybrid capture technology used in diagnostic medical applications.

Plaintiff Enzo has alleged that Digene is infringing claims 16-26, 30-40, 44-53, 73-87, 91-100 and 104-107 of the '581 Patent by making, selling and offering for sale its "Hybrid Capture" diagnostic products. This action began on March 15, 2002 when Digene filed a Summons and Complaint for Declaratory Judgment. Enzo filed a separate lawsuit for patent infringement on March 20, 2002. During a May 2, 2002 status conference, the Court suggested that the parties stipulate to a dismissal of Digene's declaratory judgment Complaint without prejudice and proceed with Enzo's patent infringement Complaint. The Court further explained that Digene would be permitted to bring other claims

against any Enzo entity, including Enzo Biochem, as permissive counterclaims. Thereafter, the parties filed a Stipulated Proposed Scheduling Order dismissing Digene's declaratory judgment action without prejudice, and the parties agreed to proceed with all pending and all related claims in Enzo's patent infringement action. Additionally, Digene filed Counterclaims against Enzo and Enzo Biochem.

Pursuant to the original stipulated scheduling order in this case, the deadline to amend pleadings was July 26, 2002. (D.I. 17). On December 12, 2002, the parties stipulated to extend several deadlines such as: 1) fact discovery; 2) expert reports; 3) rebuttal expert reports; 4) expert discovery; and 5) the dispositive motion cut-off date. (D.I. 61). On February 3, 2003, after conducting discovery, Digene filed a Motion to Amend Its Answer and Counterclaims to include a defense/counterclaim of inequitable conduct. (D.I. 83). Thereafter, on Wednesday June 4, 2003, the Court extended fact discovery as to Digene's Business Tort Counterclaims (Counterclaims III-V) until August 15, 2003. This Memorandum Opinion addresses Digene's Motion to Amend. (D.I. 83).

## **II. The Parties' Contentions**

Digene contends that its motion to amend is properly and timely filed pursuant to Federal Rule of Civil Procedure 15(a) ("Rule 15(a)") and also contends that Enzo would not be

prejudiced by the addition of an inequitable conduct defense/counterclaim at this juncture. (D.I. 84 at 3). Specifically, Digene argues that it served its first set of interrogatories and document requests on or about May 28, 2002, but written responses were not provided by Enzo until August 5, 2002. Further, Digene points out that document production did not occur until November 18, 2002, when six thousand pages of documents were produced. Id. at 2. Voluminous document production continued on December 20, 2002, when two thousand additional pages were produced and on December 25, 2002 another twenty-one thousand pages of documents were produced. Id. Also, during this discovery period Digene argues that it served several deposition notices for the two named inventors of the '581 Patent as well as the attorney who prosecuted the '581 Patent on October 29, 2002; however, the inventors were not made available for depositions until December 18 and 19, 2002. Further, Digene asserts that Enzo originally designated the entire deposition transcripts of the '581 Patent inventors, Drs. Englehardt and Rabbani, as "outside attorneys' eyes only" pursuant to the Protective Order in this case.

Digene contends that the deposition testimony of Drs. Englehardt and Rabbani provide clear evidence of Enzo's violation of 37 C.F.R. § 1.56(a) and that based upon that evidence, Digene took immediate steps to prepare its defense and counterclaim.

Id. at 3. Digene contends that on January 7, 2003, it requested that Enzo remove the confidentiality restriction, or at a minimum, reduce the confidentiality restriction so that Digene's counsel could discuss the proposed amendment with their clients. Id. Enzo provided such redesignation on January 17, 2003 and on January 23, 2002, Digene's counsel provided a courtesy copy of the proposed amended answer and counterclaim to Enzo's counsel, requesting Enzo's consent to the filing of an amended answer and counterclaim. Id. Enzo refused, and on February 3, 2003, Digene filed a motion for leave to amend its answer and counterclaims. Id. Digene contends that its request is timely given the late discovery of the pertinent information, and argues that Enzo will not be prejudiced by the amendment because it has already voluntarily supplemented its responses to Enzo's previously served written discovery requests concerning the proposed defense and counterclaim, thereby obviating any need for Enzo to serve additional discovery requests concerning the proposed defense and counterclaim. Id. at 5.

In response, Enzo contends that since Digene's motion to amend is untimely under the Scheduling Order, the motion should be judged by the heightened "good cause" standard of Federal Rule of Civil Procedure 16(b) ("Rule 16(b)"), not the liberal standard of Rule 15(a). (D.I. 92 at 2). Enzo argues that Digene's motion to amend is untimely because it comes more than six months after

the Scheduling Order deadline for amending pleadings. Id. Also, Enzo argues that Digene has not shown good cause for this delay nor could it, as each "fact" it relies on for its inequitable conduct claim comes from the public prosecution history of the '581 Patent. Id. Further, Enzo argues that Digene's inequitable conduct claim is futile to the extent that it relies on the legally unsound contention that an applicant's argument to the PTO about the effect or consequences of papers and references that are before it can constitute inequitable conduct. Id. Finally, Enzo argues that the addition of the inequitable conduct claims would be prejudicial because it would substantially change the theory on which the case has been proceeding, forcing Enzo to engage in significant new preparation after the close of discovery. Id.

In rebuttal, Digene contends that it has "good cause" for amending the Complaint, because it did not acquire a good faith Rule 11 basis for alleging materiality and intent to deceive the PTO until receiving discovery that was made available December 18-19, 2002. Further, Digene asserts that, although counsel began to prepare the defense, they had to seek leave from Enzo to redesignate the deposition transcripts of Drs. Rabbani and Englehardt so that Digene could discuss the amendment with their client. This redesignation did not occur until January 17, 2003, after which time Digene sought consent from Enzo to amend the

Complaint. Digene further contends that its proposed amendment is not futile, because it is beyond dispute that at least two sworn statements presented by the applicants during the prosecution history of the '581 Patent were knowingly false. (D.I. 99 at 5).

### **III. Discussion**

Ordinarily motions for leave to amend pleadings are properly considered under Rule 15(a), which provides that a party may amend its pleading "by leave of the court . . . and leave shall be freely given when justice so requires." Fed. R. Civ. P. 15 (a). The grant or denial of a motion to amend is within the discretion of the Court. Foman v. Davis, 371 U.S. 178, 182, 9 L. Ed. 2d 222, 83 S. Ct. 227 (1962). However, the Supreme Court of the United States has cautioned that leave should be freely granted unless there is an apparent reason for denying a request such as: undue delay, bad faith, dilatory motive, prejudice or futility of the claims. Id.; see also In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1434 (3d Cir. 1997). Enzo contends that the "good cause" standard of Rule 16(b) is implicated in this case because a Scheduling Order, with a deadline to amend pleadings by July 26, 2002, is in effect and that Schedule should not be "modified except upon a showing of good cause." Fed. R. Civ. P. 16 (b).

#### **A. Rule 15**

The Court concludes that Digene has met the standard under Rule 15(a) for leave to amend pleadings. First, the Court recognizes that although the Federal Circuit has not ruled on whether the "pleading with particularity" requirement of Federal Rule of Civil Procedure 9(b) ("Rule 9(b)") applies to claims of inequitable conduct, this district and the majority of the federal courts that have addressed the issue, have held that Rule 9(b) applies to inequitable conduct claims in patent cases. See, e.g., Point DX, Inc. v. Voxar Ltd., 2002 WL 31189696, at \*1 (M.D.N.C. Sept. 20, 2002) (applying Rule 9(b) to inequitable conduct claims); Nortel Networks Ltd. v. Kyocera Wireless Corp., No. 3:02-CV-0032-D, 2002 U.S. Dist. Lexis 17845, at \*5 (N.D. Tex. Sept. 20, 2002) (same); Davidson v. Cao, 211 F. Supp. 2d 264, 285 (D. Mass. 2002) (same); Agere Sys. Guardian Corp. v. Proxim, Inc., 190 F. Supp. 2d 726, 734 (D. Del. 2002) (same); ASM Am., Inc. v. Genus, Inc., 2002 WL 24444, at \*2 (N.D. Cal. Jan. 9, 2002) (same); In re Papst Licensing, GMBH Patent Litig., 174 F. Supp. 2d 446, 448 (E.D. La. 2001) (same); Moore U.S.A., Inc. v. Standard Register Co., 139 F. Supp. 2d 348, 359 (W.D.N.Y. 2001) (same); Union Carbide Chem. & Plastics Tech. Corp. v. Shell Oil Co., No. 99-CV-274-SLR, 2000 WL 1481015, at \* 2 (D. Del. Sept. 29, 2000) (same); Rhone-Poulenc Agro S.A. v. Monsanto Co., 73 F. Supp. 2d 537, 538 (M.D.N.C. 1999) (same); Miller Pipeline Corp. v. British Gas PLC, 69 F. Supp. 2d 1129, 1135 (S.D. Ind. 1999)

(same); Systemation, Inc. v. Engel Indus., Inc., 183 F.R.D. 49, 51 (D. Mass. 1998) (same); Environ Prods., Inc. v. Total Containment, Inc., 951 F. Supp. 57, 59 (E.D. Pa. 1997) (same); Regents of the Univ. of Cal. v. Oncor Inc., 44 U.S.P.Q.2d 1321, 1330 (N.D. Cal. 1997) (same); Heidelberg Harris, Inc. v. Mitsubishi Heavy Indus., Inc., 42 U.S.P.Q.2d 1369, 1372 (N.D. Ill. 1996) (same); Advanced Cardiovascular Sys. Inc. v. Medtronic Inc., 989 F. Supp. 1237, 1247 (N.D. Cal. 1996) (same).

The Court finds the Advanced Cardiovascular case particularly persuasive on this issue. In Advanced Cardiovascular, the Defendant sought to amend its answer to add a defense of inequitable conduct after conducting a deposition. The Plaintiff claimed that the Defendant unduly delayed raising such a defense because all of the facts were known to the Defendant long before the deposition and were contained in the Patent Office file histories. Advanced Cardiovascular Sys., 989 F. Supp. at 1247. The Court distinguished the situation from other cases and noted that instead of asserting a new theory based on otherwise pled facts, the Defendant sought leave to amend "to raise a new theory based on a new set of facts only recently confirmed by SciMed." Id. Further, the court noted that because the legal theory of inequitable conduct was at issue, the Rule 9(b) "pleading with particularity" requirement was implicated and the Defendant "was entitled to confirm factual

allegations before amending to include the inequitable conduct defense." Id.

Similarly, in this case, after taking the depositions of the two inventors of the '581 Patent, Drs. Englehardt and Rabbani, Digene contends that it obtained clear evidence of Enzo's violation of the requirement of 37 C.F.R. § 1.56 (a). For example, Digene asserts that Drs. Rabbani and Englehardt submitted a sworn declaration to the PTO in which they stated that the Englehardt, et al. reference disclosed more than "two affinities." (D.I. 99, Ex. 1 at ¶ 17). However, at his deposition, Digene alleges that Dr. Englehardt testified that the prior art disclosed as many as five affinities. (D.I. 99, Ex. 2 Englehardt Dep. at 101-107, 151-156). Further, Digene points out that the inventors also swore that the prior art did not teach "solution phase" hybridization. (D.I. 99, Ex. 1, at ¶ 17). However, Digene contends that this assertion was contradicted in Dr. Englehardt's deposition testimony. (D.I. 99, Ex. 1, Englehardt Dep. at 81-82). In its Proposed Amended Counterclaim and Answer Digene contends that the inequitable conduct of the inventors included: 1) misrepresentation of the effective filing date of the subject matter claimed in the '581 Patent ; 2) mischaracterization of the state of the prior art; 3) mischaracterizing/withholding material prior art; 4) engaging in the deceptive practice of misleading the Examiner(s) through the

repeated submission of claims drawn to subject matter unpatentable, which claims were repeatedly buried amongst large number of other claims in order to "slip them past the Examiner." (D.I. 83, Ex. 1 at 5, ¶5).

On the record presented, the Court concludes that Digene is pleading a new legal theory based on a new set of facts, which were recently confirmed by the depositions of Drs. Englehardt and Rabbani. Although Enzo contends that the facts underlying the inequitable conduct allegations were available to Digene in the public prosecution history of the '581 Patent, the Court concludes that since the Rule 9(b) "pleading with particularity" requirement is implicated with regard to an inequitable conduct claim, Digene was prudent and possibly required to confirm the factual allegations through discovery. Further, the Court finds that Digene did not unduly delay the filing of its Motion to Amend because: 1) the depositions were taken on December 17 and 18, 2002; 2) On January 7, 2003, Digene requested that Enzo remove the confidentiality restriction so that it could discuss the depositions with its client which occurred on January 17, 2003; 3) On January 23, 2003 Digene requested that Enzo consent to its proposed Amendment, and they refused; and 4) on February 3, 2003, Digene filed its motion to amend. Based on these facts, it is clear that Digene's counsel was timely in seeking the amendment. Thus, the Court concludes that there was no undue

delay and Digene did not have a dilatory motive in seeking to amend its Complaint. In addition, the Court concludes that Enzo will not be prejudiced by the addition of such a defense/counterclaim since Digene has already voluntarily supplemented its responses to Enzo's previously served written discovery requests concerning the proposed defense and counterclaim.

The Court may also deny leave to amend based on the fact that an amendment would be futile. Agere, 190 F. Supp. 2d at 736-737. An amendment is deemed futile if it could not withstand a motion to dismiss. Satellite Fin. Planning Corp. v. First Nat'l Bank, 646 F. Supp. 118, 120 (D. Del. 1986). As a general matter, patent applicants and their patent attorneys have a duty of candor, good faith and honesty in their dealings with the PTO. 37 C.F.R. § 1.56(a). The duty of candor, good faith and honesty includes the duty to submit truthful information and the duty to disclose to the PTO information known to the patent applicants or their attorneys which is material to the examination of the patent application. Elk Corp. of Dallas v. GAF Bldg. Materials Corp., 168 F.3d 28, 30 (Fed. Cir. 1999). Breach of the duty of candor, good faith and honesty may constitute inequitable conduct. Id. If it is established that a patent applicant engaged in inequitable conduct before the PTO, the entire patent application so procured is rendered unenforceable. Kingsdown

Medical Consultants v. Hollister Incorporated, 863 F.2d 867, 877 (Fed. Cir. 1988).

To establish inequitable conduct due to the failure to disclose material information or the submission of false information, the party raising the issue must prove by clear and convincing evidence that (1) the information is material; (2) the knowledge of this information and its materiality is chargeable to the patent applicant; and (3) the applicant's submission of false information or its failure to disclose this information resulted from an intent to mislead the PTO. Id. Information is deemed material if there is a substantial likelihood that a reasonable Examiner would have considered the material important in deciding whether to issue the application as a patent. See Elk Corp., 168 F.3d at 31.

In this case, Digene contends that the inventors of the '581 Patent made several material misrepresentations to the PTO during the prosecution of the '581 Patent including misrepresentations about what the inventors thought the prior art disclosed or taught and what the effective filing date was for the material contained in the '581 Patent. While the Court recognizes that the attempt of a patent applicant to distinguish its patent from the prior art does not by itself constitute a material omission or misrepresentation, the Court cannot conclude with certainty, at this juncture, that Digene can "prove no set

of facts in support of [its] claim which would entitle [it] to relief," given that it has alleged misrepresentations about things such as the effective filing date and mischaracterizing and withholding prior art. Conley v. Gibson, 355 U.S. 41, 45-46, 2 L. Ed. 2d 80, 78 S. Ct. 99 (1957) (outlining standard for motion to dismiss under 12 (b)(6)). Therefore, the Court concludes that Digene's Motion to Amend pursuant to Rule 15(a) should be granted.

#### **B. Rule 16**

With regard to the "good cause" requirement of Rule 16(b), the Court concludes that Digene has demonstrated "good cause" to amend its Answer and Counterclaim as required by Rule 16(b). Rule 16(b) provides that, "[a] schedule shall not be modified except on a showing of good cause." Fed. R. Civ. P. 16 (b). First, the Court notes that the Scheduling Order has been modified several time to serve the interests of the parties. See, e.g., D.I. 31, 38, 60, 61. Further, the Court concludes that Digene filed its amendment soon after it was able to satisfy the pleading requirements of Rule 9(b). Given that the Court has already determined that there was no undue delay or a likelihood of prejudice to Enzo, the Court concludes that Digene has satisfied the "good cause" requirement of Rule 16, and accordingly, the Motion to Amend (D.I. 83) should be granted.

An appropriate Order will be entered.

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ENZO LIFE SCIENCES, INC., :  
 :  
Plaintiff/Counterclaim Defendant, : Civil Action No. 02-212-JJF  
 :  
 v. :  
 :  
DIGENE CORPORATION, :  
Defendant/Counterclaim Plaintiff :  
 v. :  
ENZO BIOCHEM, INC., :  
 :  
Additional Counterclaim Defendant. :

**ORDER**

NOW THEREFORE, For The Reasons discussed in the Memorandum Opinion issued this date, IT IS HEREBY ORDERED this 3rd day of July 2003, that Digene Corporation's Motion For Leave to Amend Answer and Counterclaims (D.I. 83) is GRANTED.

JOSEPH J. FARNAN, JR.  
UNITED STATES DISTRICT JUDGE